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EXAMINER	
SOREY, ROBERT A	
ART UNIT	PAPER NUMBER
3626	

NOTIFICATION DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

chicago.patents@klgates.com

Office Action Summary	Application No.	Applicant(s)	
	10/749,099	MIHAI ET AL.	
	Examiner	Art Unit	
	ROBERT SOREY	3626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08/13/2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-15,17-19 and 21-28* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-15,17-19 and 21-28* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *08/26/2009*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 09/16/2009 has been entered.

Status of Claims

2. In the amendment filed 08/13/2009, the following occurred: claims 1, 8-10, 13-15, 17, 18, 23, and 24 were amended; claims 16 and 20 were cancelled. Claims 1-15, 17-19, and 21-28 are presented for examination.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. **Claims 1, 15, 18, and 24** are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

5. As per claim 1, Applicant teaches “a hub connected to (i) the plurality of medical devices and (ii) a first central computer” but then teaches “wherein the plurality of medical devices and the portable remote user interface communicate directly with the first central computer”. It is unclear how, if the plurality of medical devices are

connected to the first central computer though the hub, the plurality of medical devices can be "directly" connected to the first central computer. Or is the hub even involved in the medical device(s) and portable remote user interface communication with the first central computer? Strictly, what is claimed is a hub connecting the medical devices and the fist central computer, and the hub could be viewed as unrelated to the medical devices and portable remote user interface communicating directly with the first central computer – i.e. connected without service of the hub. Claims 15, 18, and 24 are rejected for similar reasons.

6. As per claim 28, Applicant teaches “wherein the central computer comprises a first server and a second separate server”, but it is unclear as to what this could mean – a server at least a processor with memory, it is a computer. Applicant is claiming a computer comprised of two servers - what is going on here? Are there 3 computers? Are there two servers and a computer? Do the servers share processors in the central computer? Is the hard drive partitioned or are there two separate memories? How would Applicant draw this claim?

Nonfunctional Descriptive Material

7. As per claims 1-6, 15, 18, and 24, the Examiner has placed little weight on the functional feature sets and the data types since the effect of said feature sets and data types on the claimed system and method was not made clear in the claims and did not effect or alter the claimed invention. Therefore, the functional feature sets and data types in the cited claims are nonfunctional descriptive material and are given little weight for the purposes of examination. The Examiner has cited portions of the prior art

that read on the nonfunctional descriptive material in the claims where convenient. See: Ex parte Herman Mathias, Appeal No. 2005-1851, Application No. 09/612788; and Ex parte James Prescott Curry, Appeal No. 2005-0509, Application No. 09/449237.

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

9. **Claims 1-11, 13-15, 17-19, 21, and 23** are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent Application Publication 2002/0038392 to De La Huerga in view of U.S. Patent Application Publication 2002/0093537 to Bocioned further in view of U.S. Patent Application Publication 2003/0084024 to Christensen.

10. As per claim 1, De La Huerga teaches a healthcare system for a care-giving facility, comprising:

--*a plurality of medical devices* (Fig. 26, ele. 100a and 100b)(see: De La Huerga, paragraphs 187, is met by IV pumps 100a and 100b);

--*a hub connected to (i) the plurality of medical devices and (ii) a first central computer* (Fig. 26, ele. 260; and Fig. 26A, ele. 274 and 620)(see: De La Huerga, paragraph 187, 192, and 194, hub is met by transponder 274, which is linked to a first central computer - processor 620);

--*the first central computer having a first database* (Fig. 26A, ele. 622)(see: De La Huerga, paragraphs 192, 199, and 200, is met by the memory 622) *and a first functional*

feature set associated with data and functions related to the plurality of medical devices (see: De La Huerga, paragraph 208, is met by controller controlling pump units by modifying medicant delivery including instructions to the physician; paragraph 211, is met by instructions to the pumps; paragraph 215, is met by controller determining excess capacity by checking the database; paragraphs 228 and 233, is met by controller storing in its memory fist time T1 and based on that time the controller activates the pump unit to deliver a medicant; paragraph 237, is met by controller in communication such that infusion delivery parameters can be altered based on current vital signs; paragraph 240, is met by the controller setting delivery parameters to be consistent when changing medication bags of the same prescription; paragraph 273, is met by controller able to adjust flow rate, duration, dose, etc.; paragraph 277, controller used to control virtually all aspects of pump operation and monitoring; and paragraph 294, is met by controller automatically creating notes when it monitors a dose increase due to increase in patient's blood pressure above a benchmark), *wherein the plurality of medical devices communicate directly with the first central computer* (Fig. 26, ele. 255a and 255b)(see: De La Huerga, paragraph 195, is met by connections 255 being cabled or wireless, and linking the pumps to the controller, the controller utilizing a transponder to communicate information to the processor and memory; and paragraph 273, is met by connection 255 being wireless);

--a second central computer having a second database (Fig. 31, ele. 630 and 632)(see: De La Huerga, paragraphs 243, 259, 260, 268, and 271, is met by server 630; and paragraph 320, is met by computer system 630 with database 632) *and a second*

functional feature set (see: De La Huerga, paragraphs 243, 259, 260, 268, and 271, is met by server 630 performs validation and error checking functions, information accuracy checks, and performs independent verification processes; and paragraph 320, is met by computer system 630 with database 632, including components of dispensed IV medication), *wherein the first central computer is securely connected to the second central computer, wherein the plurality of medical devices do not communicate directly with the second central computer* (Fig. 26, ele. 270 and 272)(see: De La Huerga, paragraph 270 and 271, is met by the controller connection to server); *and*

As per the limitation:

--a portable remote user interface; and subsequent teachings of the *portable remote user interface* connected to the first central computer including *wherein the portable remote user interface can receive data from the second database relating to the second functional feature set of the second central computer through the first central computer.*

De La Huerga ostensibly teaches the limitation by stating that the controller may be a personal computer, a PDA, or other hand held device (see: De La Huerga, paragraph 197); however, addressing the alternative situation in which De La Huerga does not teach said limitation including the desired configuration, the limitation is rejected here in view of Bocioned's teachings of a portable remote user interface (e.g., palmtop, laptop, mobile phone, home workstation) connected to a server in communication with an intravenous pump (Fig. 1)(see: Bocioned, paragraphs 17-21).

As per the limitation:

--*wherein the first database is a subset of the second database*

De La Huerga ostensibly teaches the limitation by stating that the server archives all standing infusion orders (see: De La Huerga, paragraph 243); however, addressing the alternative situation in which De La Huerga does not teach said limitation with the desired configuration, the limitation is rejected here further in view of Christensen's teachings of a first and second database that are able to work in a coordinated manner in which the second database reflects or contains the same information as the first database (see: Christensen, paragraph 61).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of De La Huerga, Bocioned, and Christensen. The well known elements described are merely a combination of old elements, and in the combination, each element merely would have performed the same function as it did separately, and one of ordinary skill in the art would have recognized that the results of the combination were predictable.

11. As per claim 2, De La Huerga teaches the invention substantially as claimed, see discussion of claim 1, and further teaches:

--*the first functional feature set comprises at least one of a volumetric infusion pump feature* (see: De La Huerga, paragraph 208, is met by controller controlling pump units by modifying medicant delivery including instructions to the physician; paragraph 211, is met by instructions to the pumps; paragraph 215, is met by controller determining excess capacity by checking the database; paragraphs 228 and 233, is met by controller storing in its memory fist time T1 and based on that time the controller

activates the pump unit to deliver a medicant; paragraph 237, is met by controller in communication such that infusion delivery parameters can be altered based on current vital signs; paragraph 240, is met by the controller setting delivery parameters to be consistent when changing medication bags of the same prescription; paragraph 273, is met by controller able to adjust flow rate, duration, dose, etc.; paragraph 277, controller used to control virtually all aspects of pump operation and monitoring; and paragraph 294, is met by controller automatically creating notes when it monitors a dose increase due to increase in patient's blood pressure above a benchmark), *and a syringe pump feature* (see: De La Huerga, paragraph 330, is met by syringe injectors).

12. As per claim 3, De La Huerga teaches the invention substantially as claimed, see discussion of claim 1, and further teaches:

--the first functional feature set comprises at least one of a change pump channel feature, an administer infusion feature (see: De La Huerga, paragraph 208, is met by controller controlling pump units by modifying medicant delivery including instructions to the physician; paragraph 211, is met by instructions to the pumps; paragraph 215, is met by controller determining excess capacity by checking the database; paragraphs 228 and 233, is met by controller storing in its memory fist time T1 and based on that time the controller activates the pump unit to deliver a medicant; paragraph 237, is met by controller in communication such that infusion delivery parameters can be altered based on current vital signs; paragraph 240, is met by the controller setting delivery parameters to be consistent when changing medication bags of the same prescription; paragraph 273, is met by controller able to adjust flow rate, duration, dose, etc.;

paragraph 277, controller used to control virtually all aspects of pump operation and monitoring; and paragraph 294, is met by controller automatically creating notes when it monitors a dose increase due to increase in patient's blood pressure above a benchmark)*, a stop or discontinue infusion feature* (see: De La Huerga, paragraph 150-152, 167, 173, 208, 210, 279, and 322, is met by delivery parameters adjustment, including duration, and "OFF" and "discontinue" options; and "stop and start" buttons)*, a resume infusion feature, and a remove pump feature*.

13. As per claim 4, De La Huerga teaches the invention substantially as claimed, see discussion of claim 1, and further teaches:

--the second functional feature set comprises at least one of a patient management feature, an item management feature, a facility management feature, a messaging feature (see: De La Huerga, paragraphs 243, 259, 260, 268, and 271, is met by server 630 performs validation and error checking functions, information accuracy checks, and performs independent verification processes; and paragraph 320, is met by computer system 630 with database 632, including components of dispensed IV medication)*, an alarms/alerts feature* (see: De La Huerga, paragraphs 211, 243, is met by alert activator, and indicator activation), *a billing interface feature* (see: Bocioned, paragraph 19, is met by insurance and billing information accessible with remote devices including a palmtop)*, a formulary interface feature, a lab results interface feature, an inventory tracking feature, a clinician administration feature, an order entry feature, a pharmacy feature, a user interface feature, a user interface and clinician association feature, a volumetric infusion pump feature, and a syringe pump feature.*

14. As per claim 5, De La Huerga teaches the invention substantially as claimed, see discussion of claim 1, and further teaches:

--the first database comprises at least one of pump data (see: De La Huerga, paragraph 151, 152, 167, 208, 210, 273, and 322, is met by delivery parameters), *pump channel data, pump sub-channel data, order data, clinician data* (see: De La Huerga, paragraph 208, is met by controller controlling pump units by modifying medicant delivery including instructions to the physician; paragraph 211, is met by instructions to the pumps; paragraph 215, is met by controller determining excess capacity by checking the database; paragraphs 228 and 233, is met by controller storing in its memory fist time T1 and based on that time the controller activates the pump unit to deliver a medicant; paragraph 237, is met by controller in communication such that infusion delivery parameters can be altered based on current vital signs; paragraph 240, is met by the controller setting delivery parameters to be consistent when changing medication bags of the same prescription; paragraph 273, is met by controller able to adjust flow rate, duration, dose, etc.; paragraph 277, controller used to control virtually all aspects of pump operation and monitoring; and paragraph 294, is met by controller automatically creating notes when it monitors a dose increase due to increase in patient's blood pressure above a benchmark)*, patient data, user interface data, medical device data, hub data, titration data, comparison data, alarm data, escalation data, hub alarm data, pump alarm data, channel alarm data, and alarm history data.*

15. As per claim 6, De La Huerga teaches the invention substantially as claimed, see discussion of claim 1, and further teaches:

--the second database comprises at least one of patient management data (see: De La Huerga, paragraphs 192, 199, and 200, is met by memory with stored patient ID), *item management data, facility management data, messaging data* (see: De La Huerga, paragraphs 243, 259, 260, 268, and 271, is met by server 630 performs validation and error checking functions, information accuracy checks, and performs independent verification processes; and paragraph 320, is met by computer system 630 with database 632, including components of dispensed IV medication)*, alarms/alerts data , inventory tracking data, a clinician administration data, order entry data, user interface and clinician association data.*

16. As per claim 7, De La Huerga teaches the invention substantially as claimed, see discussion of claim 1, and further teaches:

--the first central computer is operably connected to the second computer through at least one of a dedicated TCP/IP hard-wired connection, a high speed, low latency virtual private network, and a public or shared infrastructure utilizing encryption through a fiber optic connection, a microware connection, or a high speed wireless connection (see: De La Huerga, paragraphs 149, 194, 195, and 273, is met by wireless connections).

17. As per claim 8, De La Huerga teaches the invention substantially as claimed, see discussion of claim 1, and further teaches:

--the second central computer sends data from the second database to the first central computer in a first standard protocol, and the first central computer sends the data to the portable remote user interface in a second standard protocol (see: De La

Huerga, paragraphs 145-151, 194, 195, and 211, is met by the plurality of protocols including: an Internet protocol, Bluetooth protocol, and IRDA protocol).

18. As per claim 9, De La Huerga teaches the invention substantially as claimed, see discussion of claim 1, and further teaches:

--the second central computer sends second data from the second database to the first central computer, wherein the first central computer combines the second data with first data from the first database with the second data, and wherein the first central computer sends the combined fist and second data to the portable remote user interface for display on a display of the user interface (see: De La Huerga, paragraph 149-151, 211, 285, and 289-291, is met additional patient information obtained from remote facility server and displayed on interface screen; is met by the controller activating an indicator, or alert displaying patent's name, on the interface via the infusion controller; and is met by altering infusion status parameters displayed on the user interface with data entered at the controller or infusion controller).

19. As per claim 10, De La Huerga teaches the invention substantially as claimed, see discussion of claim 1, and further teaches:

--a plurality of wireless access points through which the plurality of medical devices and the portable remote user interface communicate with the first central computer (see: De La Huerga, paragraph 41, 89, 273, and 322, is met by pump in wireless communication with the transceiver - i.e. hub - at the controller).

20. As per claim 11, De La Huerga teaches the invention substantially as claimed, see discussion of claim 1, and further teaches:

--the first central computer receives second data from the second database in the second central computer for use in a validation procedure (see: De La Huerga, paragraph 219, is met by infusion controller validating physician identification with information received from the controller; and paragraphs 243, 259, 260, 268, and 271, is met by server 630 performs validation and error checking functions, information accuracy checks, and performs independent verification processes; and paragraph 320, is met by computer system 630 with database 632, including components of dispensed IV medication).

21. As per claim 13, De La Huerga teaches the invention substantially as claimed, see discussion of claim 1, and further teaches:

--the first central computer receives data from at least one of the portable remote user interface (see: Bocioned, paragraphs 17-21) *and the plurality of medical devices* (see: De La Huerga, paragraph 277, controller used to control virtually all aspects of pump operation and monitoring),

--and determines whether the received data is valid in order to enable the first central computer to perform a further step (see: De La Huerga, paragraph 208, is met by controller controlling pump units by modifying medicant delivery including instructions to the physician; paragraph 211, is met by instructions to the pumps; paragraph 215, is met by controller determining excess capacity by checking the database; paragraphs 228 and 233, is met by controller storing in its memory fist time T1 and based on that time the controller activates the pump unit to deliver a medicant; paragraph 237, is met by controller in communication such that infusion delivery parameters can be altered

based on current vital signs; paragraph 240, is met by the controller setting delivery parameters to be consistent when changing medication bags of the same prescription; paragraph 273, is met by controller able to adjust flow rate, duration, dose, etc.; paragraph 277, controller used to control virtually all aspects of pump operation and monitoring; and paragraph 294, is met by controller automatically creating notes when it monitors a dose increase due to increase in patient's blood pressure above a benchmark).

22. As per claim 14, De La Huerga teaches the invention substantially as claimed, see discussion of claim 1, and further teaches:

--the first central computer sends operation data from at least one of the first database and the second database to the plurality of medical devices for use in the operation of the plurality of medical devices (see: De La Huerga, paragraphs 243, 259, 260, and 268-271, is met by server 630 performs validation and error checking functions, information accuracy checks, and performs independent verification processes; and paragraph 320, is met by computer system 630 with database 632, including components of dispensed IV medication).

23. As per claim 15, De La Huerga teaches a method for operating a healthcare system in a care-giving facility having a *plurality of* medical *devices*, a *portable remote* user interface, a first central computer securely connected to a second central computer having a second database, the method comprising the steps of:

--receiving medical data directly from a plurality of medical devices through a hub connected to the plurality of medical devices, the hub capable of connecting to a first

central computer (Fig. 26, ele. 100a, 100b, and 260; and Fig. 26A, ele. 274 and 620)(see: De La Huerga, paragraph 187, 192, and 194, medical devices are met by IV pumps 100a and 100b and hub is met by transponder 274, which is linked to a first central computer - processor 620);

--receiving second data from a second database in a second central computer (Fig. 31, ele. 630 and 632)(see: De La Huerga, paragraphs 243, 259, 260, 268, and 271, is met by server 630; and paragraph 320, is met by computer system 630 with database 632) *and a second functional feature set* (see: De La Huerga, paragraphs 243, 259, 260, 268, and 271, is met by server 630 performs validation and error checking functions, information accuracy checks, and performs independent verification processes; and paragraph 320, is met by computer system 630 with database 632, including components of dispensed IV medication) *and from a secure connection, wherein the plurality of medical devices are configured to not communicate directly with the second central computer* (Fig. 26, ele. 270 and 272)(see: De La Huerga, paragraph 270 and 271, is met by the controller connection to server);

--retrieving first data from a first database in a first central computer; and, utilizing a first functional feature set to process at least one of the first data (see: De La Huerga, paragraph 208, is met by controller controlling pump units by modifying medicant delivery including instructions to the physician; paragraph 211, is met by instructions to the pumps; paragraph 215, is met by controller determining excess capacity by checking the database; paragraphs 228 and 233, is met by controller storing in its memory fist time T1 and based on that time the controller activates the pump unit to

deliver a medicant; paragraph 237, is met by controller in communication such that infusion delivery parameters can be altered based on current vital signs; paragraph 240, is met by the controller setting delivery parameters to be consistent when changing medication bags of the same prescription; paragraph 273, is met by controller able to adjust flow rate, duration, dose, etc.; paragraph 277, controller used to control virtually all aspects of pump operation and monitoring; and paragraph 294, is met by controller automatically creating notes when it monitors a dose increase due to increase in patient's blood pressure above a benchmark) *and the second data*.

As per the limitation:

--receiving user data directly from a portable remote user interface; and subsequent teachings of the *portable remote user interface* connected to the hub,

De La Huerga ostensibly teaches the limitation by stating that the controller may be a personal computer, a PDA, or other hand held device (see: De La Huerga, paragraph 197); however, addressing the alternative situation in which De La Huerga does not teach said limitation including the desired configuration, the limitation is rejected here in view of Bocioned's teachings of a portable remote user interface (e.g., palmtop, laptop, mobile phone, home workstation) connected to a server in communication with an intravenous pump (Fig. 1)(see: Bocioned, paragraphs 17-21).

As per the limitation:

--wherein the first database is a subset of the second database

De La Huerga ostensibly teaches the limitation by stating that the server archives all standing infusion orders (see: De La Huerga, paragraph 243); however, addressing

the alternative situation in which De La Huerga does not teach said limitation with the desired configuration, the limitation is rejected here further in view of Christensen's teachings of a first and second database that are able to work in a coordinated manner in which the second database reflects or contains the same information as the first database (see: Christensen, paragraph 61).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of De La Huerga, Bocioned, and Christensen. The well known elements described are merely a combination of old elements, and in the combination, each element merely would have performed the same function as it did separately, and one of ordinary skill in the art would have recognized that the results of the combination were predictable.

24. As per claim 17, De La Huerga teaches the invention substantially as claimed, see discussion of claim 15, and further teaches:

--providing for sending the second data to the portable remote user interface from the first central computer (see: De La Huerga, paragraphs 243, 259, 260, 268, and 271, is met by server 630 performs validation and error checking functions, information accuracy checks, and performs independent verification processes; and paragraph 320, is met by computer system 630 with database 632, including components of dispensed IV medication; and Bocioned, paragraphs 17-21).

25. As per claim 18, De La Huerga teaches a healthcare system for a care-giving facility, comprising:

--*a plurality of medical devices* (Fig. 26, ele. 100a and 100b)(see: De La Huerga, paragraphs 187, is met by IV pumps 100a and 100b);

--*a hub connected to (i) the plurality of medical devices and (ii) a central validation computer* (Fig. 26, ele. 260; and Fig. 26A, ele. 274 and 620)(see: De La Huerga, paragraph 187, 192, and 194, hub is met by transponder 274, which is linked to a first central computer - processor 620);

--*the central validation computer having a validation database* (Fig. 26A, ele. 622)(see: De La Huerga, paragraphs 192, 199, and 200, is met by the memory 622) *and a first functional feature set associated with data and functions related to the plurality of medical devices* (see: De La Huerga, paragraph 208, is met by controller controlling pump units by modifying medicant delivery including instructions to the physician; paragraph 211, is met by instructions to the pumps; paragraph 215, is met by controller determining excess capacity by checking the database; paragraphs 228 and 233, is met by controller storing in its memory fist time T1 and based on that time the controller activates the pump unit to deliver a medicant; paragraph 237, is met by controller in communication such that infusion delivery parameters can be altered based on current vital signs; paragraph 240, is met by the controller setting delivery parameters to be consistent when changing medication bags of the same prescription; paragraph 273, is met by controller able to adjust flow rate, duration, dose, etc.; paragraph 277, controller used to control virtually all aspects of pump operation and monitoring; and paragraph 294, is met by controller automatically creating notes when it monitors a dose increase due to increase in patient's blood pressure above a

benchmark), *wherein the plurality of medical devices communicate directly and securely with the central validation computer* (Fig. 26, ele. 255a and 255b)(see: De La Huerga, paragraph 195, is met by connections 255 being cabled or wireless, and linking the pumps to the controller, the controller utilizing a transponder to communicate information to the processor and memory; and paragraph 273, is met by connection 255 being wireless);

--a second central computer having a second database and a secure connection with the central validation computer (Fig. 31, ele. 630 and 632)(see: De La Huerga, paragraphs 243, 259, 260, 268, and 271, is met by server 630; and paragraph 320, is met by computer system 630 with database 632), *and a second functional feature set* (see: De La Huerga, paragraphs 243, 259, 260, 268, and 271, is met by server 630 performs validation and error checking functions, information accuracy checks, and performs independent verification processes; and paragraph 320, is met by computer system 630 with database 632, including components of dispensed IV medication), *wherein the plurality of medical devices and the portable remote user interface are configured to not communicate directly with the second central computer* (Fig. 26, ele. 270 and 272)(see: De La Huerga, paragraph 270 and 271, is met by the controller connection to server), *and*.

As per the limitation:

--a portable remote user interface; and subsequent teachings of the *portable remote user interface* connected to the central validation computer including *wherein the portable remote user interface can receive data from the second database relating*

to the second functional feature set of the second central computer through the central validation computer.

De La Huerga ostensibly teaches the limitation by stating that the controller may be a personal computer, a PDA, or other hand held device (see: De La Huerga, paragraph 197); however, addressing the alternative situation in which De La Huerga does not teach said limitation including the desired configuration, the limitation is rejected here in view of Bocioned's teachings of a portable remote user interface (e.g., palmtop, laptop, mobile phone, home workstation) connected to a server in communication with an intravenous pump (Fig. 1)(see: Bocioned, paragraphs 17-21).

As per the limitation:

--*wherein the first database is a subset of the second database*

De La Huerga ostensibly teaches the limitation by stating that the server archives all standing infusion orders (see: De La Huerga, paragraph 243); however, addressing the alternative situation in which De La Huerga does not teach said limitation with the desired configuration, the limitation is rejected here further in view of Christensen's teachings of a first and second database that are able to work in a coordinated manner in which the second database reflects or contains the same information as the first database (see: Christensen, paragraph 61).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of De La Huerga, Bocioned, and Christensen. The well known elements described are merely a combination of old elements, and in the combination, each element merely would have performed the

same function as it did separately, and one of ordinary skill in the art would have recognized that the results of the combination were predictable.

26. As per claim 19, De La Huerga teaches the invention substantially as claimed, see discussion of claim 18, and further teaches:

--the central validation computer is securely connected to the second computer computer (Fig. 26, ele. 270 and 272)(see: De La Huerga, paragraph 270 and 271, is met by the controller connection to server).

27. As per claim 21, De La Huerga teaches the invention substantially as claimed, see discussion of claim 18, and further teaches:

--the central validation computer receives second data from the second database in the second central computer for use in a validation procedure performed by the central validation computer (see: De La Huerga, paragraph 219, is met by infusion controller validating physician identification with information received from the controller; and paragraphs 243, 259, 260, 268, and 271, is met by server 630 performs validation and error checking functions, information accuracy checks, and performs independent verification processes; and paragraph 320, is met by computer system 630 with database 632, including components of dispensed IV medication).

28. As per claim 23, De La Huerga teaches the invention substantially as claimed, see discussion of claim 21, and further teaches:

--wherein central validation computer receives first data from at least one of the portable remote user interface and the plurality of medical devices (see: De La Huerga, paragraph 208, is met by controller controlling pump units by modifying medicant

delivery including instructions to the physician; paragraph 211, is met by instructions to the pumps; paragraph 215, is met by controller determining excess capacity by checking the database; paragraphs 228 and 233, is met by controller storing in its memory fist time T1 and based on that time the controller activates the pump unit to deliver a medicant; paragraph 237, is met by controller in communication such that infusion delivery parameters can be altered based on current vital signs; paragraph 240, is met by the controller setting delivery parameters to be consistent when changing medication bags of the same prescription; paragraph 273, is met by controller able to adjust flow rate, duration, dose, etc.; paragraph 277, controller used to control virtually all aspects of pump operation and monitoring; and paragraph 294, is met by controller automatically creating notes when it monitors a dose increase due to increase in patient's blood pressure above a benchmark)*, and*

--wherein the validation procedure comprises the step of determining whether the first data matches the second data (see: De La Huerga, paragraphs 243, 259, 260, 268, and 271, is met by server 630 performs validation and error checking functions, information accuracy checks, and performs independent verification processes; and paragraph 320, is met by computer system 630 with database 632, including components of dispensed IV medication).

29. **Claim 12 and 22** are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent Application Publication 2003/0038392 to De La Huerga in view of U.S. Patent Application Publication 2003/0084024 to Christensen further in view of U.S. Patent Application Publication 2003/0105806 to Gayle et al.

30. As per claim 12, De La Huerga teaches the invention substantially as claimed, see discussion of claim 11, but fails to specifically teach:

--the validation procedure comprises the steps of receiving an XML document and determining whether the data expected to be received from the XML document is received.

However, such receiving and determining of XML documents is well known in the art as evidenced by Gayle et al. (see: Gayle et al., paragraph 26).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of De La Huerga, Bocioned, Christensen, and Gayle. The well known elements described are merely a combination of old elements, and in the combination, each element merely would have performed the same function as it did separately, and one of ordinary skill in the art would have recognized that the results of the combination were predictable.

31. As per claim 22, De La Huerga teaches the invention substantially as claimed, see discussion of claim 21, but fails to specifically teach:

--the validation procedure comprises the steps of receiving an XML document and determining whether the data expected to be received from the XML document is received.

However, such receiving and determining of XML documents is well known in the art as evidenced by Gayle et al. (see: Gayle et al., paragraph 26). It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of De La Huerga, Christensen, and Gayle et al. The well known elements

described are merely a combination of old elements, and in the combination, each element merely would have performed the same function as it did separately, and one of ordinary skill in the art would have recognized that the results of the combination were predictable.

32. **Claims 24, 25, and 27** are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent Application Publication 2002/0038392 to De La Huerga in view of U.S. Patent Application Publication 2002/0093537 to Bocioned.

33. As per claim 24, De La Huerga teaches a healthcare system for a care-giving facility, comprising:

--a plurality of medical devices (Fig. 26, ele. 100a and 100b)(see: De La Huerga, paragraphs 187, is met by IV pumps 100a and 100b);

--a hub connected to (i) the plurality of medical devices and (ii) a central validation portion of a central computer (Fig. 26, ele. 260; and Fig. 26A, ele. 274 and 620)(see: De La Huerga, paragraph 187, 192, and 194, hub is met by transponder 274, which is linked to a first central computer - processor 620);

--the central validation portion of a central computer having a validation portion of a database (Fig. 26A, ele. 622)(see: De La Huerga, paragraphs 192, 199, and 200, is met by the memory 622) *and a first functional feature set associated with the data and functions related to the plurality of medical devices and the portable remote user interface* (see: De La Huerga, paragraph 208, is met by controller controlling pump units by modifying medicant delivery including instructions to the physician; paragraph 211, is met by instructions to the pumps; paragraph 215, is met by controller determining

excess capacity by checking the database; paragraphs 228 and 233, is met by controller storing in its memory fist time T1 and based on that time the controller activates the pump unit to deliver a medicant; paragraph 237, is met by controller in communication such that infusion delivery parameters can be altered based on current vital signs; paragraph 240, is met by the controller setting delivery parameters to be consistent when changing medication bags of the same prescription; paragraph 273, is met by controller able to adjust flow rate, duration, dose, etc.; paragraph 277, controller used to control virtually all aspects of pump operation and monitoring; and paragraph 294, is met by controller automatically creating notes when it monitors a dose increase due to increase in patient's blood pressure above a benchmark), *wherein the plurality of medical devices and the portable remote user interface communicate directly and securely with the central validation portion of the central computer* (Fig. 26, ele. 255a and 255b)(see: De La Huerga, paragraph 195, is met by connections 255 being cabled or wireless, and linking the pumps to the controller, the controller utilizing a transponder to communicate information to the processor and memory; and paragraph 273, is met by connection 255 being wireless); *and*

--a second non-validation portion of the central computer having a second non-validation portion of the database (Fig. 31, ele. 630 and 632)(see: De La Huerga, paragraphs 243, 259, 260, 268, and 271, is met by server 630; and paragraph 320, is met by computer system 630 with database 632) *and a second functional feature set* (see: De La Huerga, paragraphs 243, 259, 260, 268, and 271, is met by server 630 performs validation and error checking functions, information accuracy checks, and

performs independent verification processes; and paragraph 320, is met by computer system 630 with database 632, including components of dispensed IV medication), *wherein the plurality of medical devices and the portable remote user interface are configured and arranged to not communicate directly with the second non-validation portion of the central computer and* (Fig. 26, ele. 270 and 272)(see: De La Huerga, paragraph 270 and 271, is met by the controller connection to server).

As per the limitation:

--a portable remote user interface; and subsequent teachings of the *portable remote user interface* connected to the first central computer including *wherein the portable remote user interface can receive data from the second non-validation portion of the database relating to the second functional feature set of the second non-validation portion of the central computer through the central validation portion of the central computer*

De La Huerga ostensibly teaches the limitation by stating that the controller may be a personal computer, a PDA, or other hand held device (see: De La Huerga, paragraph 197); however, addressing the alternative situation in which De La Huerga does not teach said limitation including the desired configuration, the limitation is rejected here in view of Bocioned's teachings of a portable remote user interface (e.g., palmtop, laptop, mobile phone, home workstation) connected to a server in communication with an intravenous pump (Fig. 1)(see: Bocioned, paragraphs 17-21).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of De La Huerga, and Bocioned. The well

known elements described are merely a combination of old elements, and in the combination, each element merely would have performed the same function as it did separately, and one of ordinary skill in the art would have recognized that the results of the combination were predictable.

34. As per claim 25, De La Huerga teaches the invention substantially as claim, see discussion of claim 24, but fails to specifically teach:

--the central validated portion of the central computer operates in a first environment running a first operating system (Fig. 26A, ele. 622)(see: De La Huerga, paragraphs 192, 199, and 200, is met by the memory 622)*, and the second non-validation portion of the central computer operates in a second environment running a second operating system* (Fig. 31, ele. 630 and 632)(see: De La Huerga, paragraphs 243, 259, 260, 268, and 271, is met by server 630; and paragraph 320, is met by computer system 630 with database 632).

35. As per claim 27, De La Huerga teaches the invention substantially as claimed, see discussion of claim 24, but fails to teach:

--the central computer is a single server (Fig. 26, ele. 260; and Fig. 26A, ele. 620 and 622)(see: De La Huerga, paragraphs 192, 199, and 200, is met by the memory 622 and the processor 620 in a single controller 260).

36. **Claims 26 and 28** are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent Application Publication 2003/0038392 to De La Huerga in view of U.S. Patent Application Publication 2002/0093537 to Bocioned further in view of U.S. Patent Application Publication 2003/0105806 to Gayle et al.

37. As per claim 26, De La Huerga teaches the invention substantially as claimed, see discussion of claim 25, but fails to specifically teach:

--the first and second operating systems are separated by a fire wall.

However, such firewalls are well known in the art as evidenced by Gayle et al. (Fig. 1, ele. 136)(see: Gayle et al., paragraph 22 and 37).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of De La Huerga, Bocioned, and Gayle et al. The well known elements described are merely a combination of old elements, and in the combination, each element merely would have performed the same function as it did separately, and one of ordinary skill in the art would have recognized that the results of the combination were predictable.

38. As per claim 28, De La Huerga teaches the invention substantially as claimed, see discussion of claim 24, and further teaches:

--the central computer comprises a first server (Fig. 26A, ele. 622)(see: De La Huerga, paragraphs 192, 199, and 200, is met by the memory 622) *and a second separate server* (Fig. 31, ele. 630 and 632)(see: De La Huerga, paragraphs 243, 259, 260, 268, and 271, is met by server 630; and paragraph 320, is met by computer system 630 with database 632), *wherein the central validation portion of the central computer resides in the first server* (see: De La Huerga, paragraph 208, is met by controller controlling pump units by modifying medicant delivery including instructions to the physician; paragraph 211, is met by instructions to the pumps; paragraph 215, is met by controller determining excess capacity by checking the database; paragraphs

228 and 233, is met by controller storing in its memory fist time T1 and based on that time the controller activates the pump unit to deliver a medicant; paragraph 237, is met by controller in communication such that infusion delivery parameters can be altered based on current vital signs; paragraph 240, is met by the controller setting delivery parameters to be consistent when changing medication bags of the same prescription; paragraph 273, is met by controller able to adjust flow rate, duration, dose, etc.; paragraph 277, controller used to control virtually all aspects of pump operation and monitoring; and paragraph 294, is met by controller automatically creating notes when it monitors a dose increase due to increase in patient's blood pressure above a benchmark), *wherein the plurality of medical devices communicate directly with the first central computer* (Fig. 26, ele. 255a and 255b)(see: De La Huerga, paragraph 195, is met by connections 255 being cabled or wireless, and linking the pumps to the controller, the controller utilizing a transponder to communicate information to the processor and memory; and paragraph 273, is met by connection 255 being wireless), *and wherein the second non-validation portion of the central computer resides on the second server* (see: De La Huerga, paragraphs 243, 259, 260, 268, and 271, is met by server 630 performs validation and error checking functions, information accuracy checks, and performs independent verification processes; and paragraph 320, is met by computer system 630 with database 632, including components of dispensed IV medication).

Fails to specifically teach:

--the first and second servers being separated by a fire wall

However, such firewalls are well known in the art as evidenced by Gayle et al. (Fig. 1, ele. 136)(see: Gayle et al., paragraph 22 and 37).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of De La Huerga, Bocioned, and Gayle et al. The well known elements described are merely a combination of old elements, and in the combination, each element merely would have performed the same function as it did separately, and one of ordinary skill in the art would have recognized that the results of the combination were predictable.

39. **Claim 27** is rejected again under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent Application Publication 2002/0038392 to De La Huerga in view of U.S. Patent Application Publication 2002/0093537 to Bocioned further in view of legal precedent as cited in the MPEP chapter 2144.04 parts B (Making Integral).

40. As per claim 27, De La Huerga teaches the invention substantially as claimed, see discussion of claim 24, but fails to teach:

--the central computer is a single server.

However, that the central computer is composed of a single server instead of a plurality of servers is merely a matter of obvious design choice (see: MPEP, Chapter 2144.04, part B, Making Integral).

Response to Arguments

41. Applicant's arguments from the response filed on 08/13/2009 have been fully considered and will be addressed below in the order in which they appeared.

42. In the remarks, Applicant argues in substance that (1) rejections under De La Huerga should be withdrawn because the cited prior art does not meet the current configuration and "fails to teach or suggest a plurality of medical devices, a portable remote user interface, and a hub connected to the plurality of medical devices, the hub connected to a first central computer, a central validation computer, or a central validation portion of a central computer".

The Examiner respectfully disagrees. Applicant's arguments are not persuasive.

The previously applied rejections have been modified to meet the invention as amended by Applicant – the previously cited prior art has been used differently to reject the claims and additional prior art (notably the Bocioned reference) was brought in to meet Applicant's current claim limitations.

De La Huerga teaches a plurality of medical devices (most notably IV pumps, but other devices as well) in communication with a transponder. The transponder meets Applicant's limitation of a "hub" - it performs all the desired functions. The transponder communicates to the controller processor and memory, which meets Applicant's desired first computer with database. Additionally, the controller is in communication with a server and database, which meets Applicant's desired second computer with database. The only way that the medical devices (including IV pumps) can communicate with the server (and associated database) is through the controller, which meets Applicant's

limitation of indirect communication with the second computer. Bocioned teaches the portable remote user interface (e.g., palmtop, laptop, mobile phone, home workstation), which Bocioned teaches is in communication with a server in communication with an intravenous pump. Christensen teaches a first and second database that are able to work in a coordinated manner in which the second database reflects or contains the same information as the first database. Used In obvious combination these references meet Applicant's claims where appropriately cited.

Additionally, Applicant argues that the isolation of the central computer, and in general the claimed configuration, is distinct from the prior art because "first central computer can be configured to hold data and perform actions related to sending and receiving data to and from hubs, medical devices, portable user interfaces and the second central computer, as well as comparing prescription parameters; relaying notifications, messages, alarms and alerts; and compiling pump data" and "the second central computer can be configured to interface, for example, with a pharmacy system to provide drug and patient information, and interface with the first computer to provide patient, nurse, clinician and order information", however, none of this is material to the system (or method) – this configuration is a matter of design choice that does not provide unexpected results or functionality over previously existing systems (or methods) that contain the same elements. The MPEP presents legal precedent concerning matters of design choice (see: MPEP, Chapter 2144.04), for example, and makes clear that separating or integrating the data or functions performed by a

computer or plurality of computers is a matter of obvious design choice if it does not result in a new and unexpected result.

Finally, Applicant's configuration can be found in many non-medical related areas. For example, U.S. Patent 6,081,786 to Barry clearly shows in Fig. 3 a plurality of client computers (desktop computers meet Applicant's broadly claimed "medical devices" as medical staff use computers for a plethora of functions) connected to local server computer with associated database and then to a central server computer with associated database. It is no great leap to use such configurations in a medical setting, and such a use is obvious if it does not produce new and unexpected results. Further still, U.S. Patent 5,822,544 teaches yet another system configuration that meets Applicant's claimed configuration, this one explicitly relevant to the medical field, IV pumps, etc. as claimed by Applicant.

As per the Christensen reference, it is relevant to the claimed invention because it teaches database relationships among a plurality of databases, and the Examiner is in general agreement with Applicant's assessment that "Christensen is cited merely to show a first and second database that are able to work in a coordinated manner in which the second database reflects or contains the same information as the first database".

43. In the remarks, Applicant argues in substance that (2), regarding the Examiner's Official Notice, "Applicant respectfully traverse the notion that connecting medical devices to computers wirelessly was common, old, and well known to someone of

ordinary skill at the time the invention was made. Applicants note that the Office Action does not include any evidence to support the Official Notice".

The Examiner respectfully disagrees. Applicant's arguments are not persuasive.

Applicant has attempted to challenge the Examiner's taking of Official Notice. There are minimum requirements for a challenge to Official Notice:

(a) In general, a challenge, to be proper, must contain adequate information or arguments so that *on its face* it creates a reasonable doubt regarding the circumstances justifying the Official Notice

(b) Applicants must seasonably traverse (challenge) the taking of Official Notice as soon as practicable, meaning the next response following an Office Action. If an applicant fails to seasonably traverse the Official Notice during examination, his right to challenge the Official Notice is waived.

Applicant has not provided adequate information or arguments so that *on its face* it creates a reasonable doubt regarding the circumstances justifying the Official Notice. Therefore, the presentation of a reference to substantiate the Official Notice is not deemed necessary.

Bald statements such as, "Applicants respectfully traverse the notion that" or "Applicants note that the Office Action does not include any evidence to support the Official Notice", are not adequate and do not shift the burden to the Examiner to provide evidence in support of the Official Notice.

Regardless, the rejection has been changed because support for rejection was found within the De La Huerga reference of record. Specifically, De La Huerga teaches IV pumps in wireless communication with the transceiver - i.e. the hub at the controller.

44. The Examiner has considered Applicant's specification and claims. The record shows that the Examiner has as of yet not identified allowable subject matter. Applicant is urged to carefully consider all available options before proceeding.

Conclusion

45. Any inquiry concerning this communication or earlier communications from the examiner should be directed to ROBERT SOREY whose telephone number is (571)270-3606. The examiner can normally be reached on Monday through Friday, 8:30AM to 5:00PM (EST).

46. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Gilligan can be reached on (571)272-6770. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

47. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only.

For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/R. S./
Examiner, Art Unit 3626
14 December 2009

/Robert Morgan/
Primary Examiner, Art Unit 3626